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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/766,350	12/13/96	CHATTERJEE M	304142000321

HM22/0926

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EXAMINER	
BURKE, J	
ART UNIT	**PAPER NUMBER**
1642	25

DATE MAILED: 09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/766,350	Chatterjee et al
Examiner	**Group Art Unit**
Julie E. Burke (Reeves), Ph.D.	1642

☒ Responsive to communication(s) filed on *4 Oct 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24 and 26-68* is/are pending in the application.

Of the above, claim(s) *6-19, 38, 41, 44-53, 57, and 58* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5, 20-24, 26-37, 39, 40, 42, 43, 54-56, and 59-68* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.

2. The following Office Action contains some NEW GROUNDS of rejection.

3. Claims 62-68 have been added. Claims 1-24 and 26-68 are pending. Claims 20-22, 26, 29, 30, 31-33, 35, 39, 43 have been amended. Claims 1-5, 20-24, 26-37, 39-40, 42-43, 54-56 and 59-68 are under examination.

4. This application contains claims 6-19, 38, 41, 44-53, 57-58 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

5. The objection to the disclosure is withdrawn.

Claim Objections

6. Claim 20 is objected to because of the following informalities: the term "complementarity" appears to be misspelled. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

7. Claims 26 and 35 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Newly amended Claim 26 in indefinite for now reciting "wherein the polypeptide contains a sequence of at least 2 contiguous amino acids which are identical in forward or reverse orientation to 2 contiguous amino acids of a tandem repeat sequence in human mucin from human milk fat globule" because it is not clear what is meant by the word "tandem repeat sequence". Does this refer to the 20 amino acid tandem repeats or any two or three peptide repeats that may be found in any human mucin from milk fat globule? Further, the amino acid sequence for a human mucin from HMFG is apparently not known. The Specification teaches that HMFG "has several proteinaceous (and thus antigenic) components. As used herein, it refers to a semi-purified extract of an HMFG-expressing breast cancer cell line, along with antigenically related substances, including HMFG expressed on breast cancer cells and more highly purified purifications" (page 20, lines 12-21). Because the claim does not recite which HMFG sequence, one skilled in the art would not be able to determine the metes and bounds of the claims.

b. Newly amended Claim 35 stands indefinite for reciting "humanized antibody" because only murine CDRs are recited. The claims fail to include any reference to human framework regions or human constant regions. It is impossible to determine the metes and bounds of the claims.

Deposit of Biological Materials

8. The rejection of claims 1-5, 20-22, 26, 35-37, 39, 40, 42- 43, 54, 55, 56, 59-61 under 35 U.S.C. § 112, first paragraph is withdrawn in view of the statements made on pages 6-7 of the Dr. Chatterjee Declaration under 37 CFR 1.132 filed 10/4/99 as Paper no 24.

a. Applicants state that the Examiner did not provide any reasons why the declaration of Dr. M. Chatterjee, attachment to paper no 14 filed 10/8/98 was not satisfactory. As stated in the previous Office Action, the declaration of Dr. M. Chatterjee, attachment to paper no 14 filed 10/8/98 has been considered carefully but is deemed not to be persuasive because the declaration has not been signed.

b. Applicants also noted that the declaration was not required because the deposit was made before the filing date of the application. This statement is not persuasive. The specification states on page 14 that the deposit was made Jan 17, 1996, however, the application claims priority back to 60/031,306 filed 20 Dec 1995.

Applicants state that because the amino acid sequence of the heavy and light chain variable regions was provided in the specification, no deposit requirement should be required. Applicants assertion would be correct if the claims were limited to those particular amino acid sequences. In contrast, the claims recite specifically antibody produced by the deposited hybridoma. In order to practice the claimed invention, one skilled in the art would need to have access to the antibody produced by the claimed hybridoma. This antibody may differ from the antibody produced by the amino acid sequence information in view of different glycosylation patterns and in view of the lacking disclosure for constant region sequences.

9. Newly amended Claim 39, and newly added 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides which contain all six CDRS of 11D10, does not reasonably provide enablement for polypeptides which contain only one of the six CDRS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons set forth in the previous Office Action, as evidenced by Chatterjee et al, Rudikoff et al, Adair et al. (PCT GB90/02017), Panka et al and Amit et al.

a. The response set forth on page 9-10 has been considered carefully but is deemed not to be persuasive. The response argues that the claims have been amended to recite that the claimed polypeptide must have three CDRs from the light or heavy chain variable regions of 11D10. This is not persuasive because the claims do not recite the argued limitation.

10. Claims 39, 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 39, 62 and 63 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 23 filed 10/4/99. In that paper, applicant has stated that "the claims have been amended to recite that the claimed polypeptide must have three CDRs from the light or heavy chain variable regions of 11D10", and this statement indicates that the invention is different from what is defined in the claim(s) because claim 39 recites only one CDR.

Claim Rejections - 35 U.S.C. § 102

11. Claims 1-5, 20-27, 31-33, 36, 37, 39-40, 42-43, 55-56 and 59-68 are rejected under 35 U.S.C. 102(b) as being anticipated by any of

i. Chatterjee Antigen and Antibody Molecular Engineering 1994 (see page 140, Fig 1, for example)

ii. Chatterjee et al Cancer Immunol Immunother 1994 Vol 34 75-82 (See page 77, last full paragraph, for example)

iii. Chakraborty et al Proc Am Assoc Cancer Res 1994 Abstract 2963 (See Abstract);

iv. Chakraborty et al 1995 J Immunotherapy Vol 18(2) 95-103 (see page 96, col 1 "Antibodies") or

v. Charaborty et al Cancer Research Vol 55 1525-1530 4/1/95 (Information Disclosure Statement Paper no 5 filed 7/18/97).

a. The claims and references i-iv have been described in the previous office action. Newly applied Reference v recites a murine anti-idiotype antibody named 11D10 which is specific for human breast cancer milk fat globule. See Abstract. Due to the open claim language "comprising", and upon reconsideration, the reference v reads upon the claims. It is noted that Section 102(b) contains the clause the invention was "described in a printed publication in this or

a foreign country". This invention was clearly described in a publication more than one year prior to the date of application for patent in the United States.

b. The 37 CFR 1.132 declaration submitted 10/4/99 by M. Chatterjee; K. Foon and S. Chatterjee has been considered carefully but deemed not to be persuasive. The Declaratants fail to account for the role Dr. Kohler had in the invention, they merely state that he did not participate in generating or characterizing 11D10 (see page 6, of Chatterjee Declaration).

c. Further, the Declaration attempts to overcome a 102(b) rejection by stating that the 11D10 hybridoma and antibody were not publicly available. It is noted that 102(b) also bars inventions which are described in a written publication. Clearly 11D10 has been described in written publications more than a year before the filing of the US application, as evidenced above.

d. Additionally, as evidenced by the statement made on page 13 (Publication Policy) by publishing in Cancer Research Journal (reference v), the authors Chakrabroty, Mukerjee, Foon, Kohler, Ceriani and Chatterjee agreed to make freely available their hybridoma and 11D10 antibody. The declaration filed 10/4/99 do not explain how the antibody was not publicly available when this was a requirement of Cancer Research Journal. Thus the rejection is made.

12. The rejection of Claims 1-5, 20-27, 31-33, 36-37, 39-40, 42-43, 55-56 and 59-68 under 35 U.S.C. 102(f) as by any of Chatterjee et al (Antigen and Antibody Molecular Engineering 1994), Chatterjee et al (Cancer Immunol Immunother 1994 Vol 34 75-82), Chakraborty et al (Proc Am Assoc Cancer Res 1994 Abstract 2963) or Chakraborty et al (1995 J Immunotherapy

Vol 18(2) 95-103 (see page 96, col 1 "Antibodies") and Charaborty et al (Cancer Research Vol 55 1525-1530 4/1/95 Information Disclosure Statement Paper no 5 filed 7/18/97), because the inventors did not invent the work sought to be patented has been made again and maintained.

a. Claims have been described above. The instant application lists M. Chatterjee; K. Foon and S. Chatterjee as the sole inventors of the 11D10 antibody.

b. In contrast, Chatterjee et al (Antigen and Antibody Molecular Engineering 1994) lists not only M. Chatterjee and K.Foon; but also lists E. Mrozek; S. Mukerjee; R. Ceriani and H. Kohler as authors on a paper discussing the 11D10 antibody. Similarly, Chatterjee et al (Cancer Immunol Immunother 1994 Vol 34 75-82) lists H. Kohler as an author but not an inventor. Additionally, Chakraborty et al (Proc Am Assoc Cancer Res 1994 Abstract 2963) list as authors, but not inventors, the following: M. Chakraborty, A. Sherratt and K. Ceriani. Further, newly applied Charaborty et al (Cancer Research Vol 55 1525-1530 4/1/95) lists M. Chakraborty, H. Kohler Mukerjee; K. Foon, R. Ceriani and Chatterjee et al as authors.

c. From the authorship lists recited above, one skilled in the art would reasonably conclude that in addition to M. Chatterjee; K. Foon and S. Chatterjee; the authors M. Chakraborty, H. Kohler, A. Sherratt, Mrozek; S. Mukerjee; R. Ceriani also contributed to the invention. They are not listed as inventors.

d. The 37 CFR 1.132 declaration submitted 10/4/99 by M. Chatterjee; K. Foon and S. Chatterjee has been considered carefully but deemed not to be persuasive. The Declaratants

fails to account for the role Dr. Kohler had in the invention, they merely state that he did not participate in generating or characterizing 11D10 (see page 6, of Chatterjee Declaration).

13. The rejection of Claims 20, 22, 24, 26, 33, 34, 35, 36, 39, 42, 56 and 61 under 35 U.S.C. 102(e) as being anticipated by Gourlie et al (5,808,033, filed 2/93 and issued 9/98) is withdrawn in view of the amendment(s) to the claims.

14. The rejection of Claims 20, 21, 23, 26, 33, 34, 35, 36, 39, 42, 56 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Bendig et al (5,840,299, filed 11/95 and issued 11/98) is withdrawn in view of the amendment(s) to the claims.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, née Reeves, Ph.D, whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Julie E. Burke, née Reeves, Ph.D.

Primary Patent Examiner

(703) 308-7553

JULIE BURKE
PRIMARY EXAMINER